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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/198,779	11/24/1998	STEFAN A. BLEDIG	04983.0002US	2937

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EXAMINER	
ZHOU, SHUBO	
ART UNIT	**PAPER NUMBER**
1631	17

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/198,779	Applicant(s) BLEDIG ET AL.	
	Examiner Shubo "Joe" Zhou	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the c rresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12, 15, 3
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendment and request for reconsideration in Paper #18, filed on 12/27/01, is acknowledged and the amendments entered.

Currently, claims 1-2 and 13 are pending, and under consideration.

Applicant's arguments in response to the previous Office Action of 10/21/01 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous Office action are hereby withdrawn. The following rejections and/or objections are either reiterated from the previous Office action(s) or newly added, and constitute the complete set presently being applied to the instant application.

Specification

The disclosure is objected to also because it contains an embedded hyperlink and/or other form or browser-executable code. Such code is present in the specification at page 73 and elsewhere. Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP ' 608.01.

Claim Rejections-35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of th manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and use the same and shall set forth th best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 13 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

This rejection is reiterated from the previous Office action and maintained for reasons of record.

Applicants' arguments are on the ground that the specification provides specific and substantial utilities for the invention because in addition to the utilities the Examiner referred to in the previous Office action, the specification also listed other utilities, including providing a substantially purified nucleic acid sequence which encodes an enzyme, and that the Office has not shown evidence or sound scientific reasoning for the utility rejection based on sequence homology. See pages 4-5 of the communication filed 12/27/01. This is not found persuasive because firstly, just as the utilities referred to by the Examiner in the previous Office action, this utility is neither specific, nor substantial. Providing a nucleic acid sequence to a gene that is a putative enzyme does not provide a specific and substantial utility. Further, as set forth in the previous Office action, more research is needed to shown that the sequence has enzymatic activity. As set forth on pages 4-5 of the previous Office action, such clear need of further research indicates that the nucleic acids are not disclosed as to a currently available substantial utility. Thus, the claimed nucleic acids are not supported by a specific and substantial asserted utility. Furthermore, with regard to sequence homology, on page 6 of the previous Office action, the Examiner provided sound scientific reasoning based on

published art that sequence homology itself is not enough for having a same function for two sequences. For example, it is known that often even one amino acid substitution would destroy the function of the protein. In other words, two proteins with even one amino acid residue difference may have two different functions.

Claims 2 and 13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

This rejection is reiterated from the previous Office action and maintained for reasons of record. Since applicant's arguments for the above rejection under 35 U.S.C. 101 are not deemed persuasive, the arguments in response to this rejection are deemed non-persuasive for the same reasons as set forth above.

Claims 2 and 13 are rejected, as discussed below, also under 35 U.S.C. 112, first paragraph, as containing subject matter which lacks written description in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is reiterated from the previous Office action and maintained for reasons of record.

Applicants' arguments on pages 7-8 are essentially on the ground that applicants are entitled to claim an embodiment broader than disclosed and that applicants do not have to disclose all the species for a genus for satisfying the written description requirement. This is not found persuasive because as set forth in the previous Office action, there is substantial variability among the species of polynucleotides or nucleic acids encompassed within the scope of the claims because the claimed SEQ ID NO is only a fragment of any full-length gene or cDNA species, or any vector due to the use of the open language "comprising" or "consisting essentially". In view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DNAs or RNAs encompassed in claims 2 and 13, which comprise the sequence of the claimed SEQ ID NO.

Claims 1-2, and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)), the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation; (b) the amount of guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior

art; (f) the predictability of the prior art; (g) the breadth of the claims; and (h) the relative skill in the art.

Claim 1 is drawn to a nucleic acid encoding a maize or soybean methionine adenosyltransferase or a fragment thereof. However, the sequence of the nucleic acid encoding such enzyme or fragment thereof is not known in the art and not disclosed in the instant specification. Therefore, one skilled in the art does not know how to make and use the nucleic acid as a methionine adenosyltransferase or a fragment thereof.

Claims 2 and 3 are drawn to nucleic acid comprising or consisting essentially of the sequence of SEQ ID NO:1 that encodes a maize or soybean methionine adenosyltransferase. The specification asserts that the sequence of SEQ ID NO:1 encodes a polypeptide that is homologous to known methionine adenosyltransferase in other plant species. However, the prior art is unpredictable with regards to homology-based assignment of functionality to a particular target gene based on genes where the functionality is known. For example, the prior art has demonstrated that assignment of a metabolic gene to a know function based on homology comparisons provide improper functional assignment (see the homology-based methods of functional assignment of Everett et al., Nature Genetics *17*, 411-422, 1997 in light of the experimental conclusions of Scott et al., Nature Genetics *21*, 440-443, 1999). Everett et al. disclose a homology-based functional assignment to a putative, mutated sulfate transporter gene (PDS; which encodes "pendrin") identified through positional cloning in Pendred syndrome populations. The homology-based searches were carried out using BLAST and PSI-BLAST with commercial databases using human pendrin as the query

sequence. The conclusions of Everett et al. based upon the homology comparisons were that pendrin was a transporter of sulfate. However, experimental studies by Scott et al., clearly demonstrate that pendrin, which has: 1) 29% homology to the rat sulfate-ion transporter encoded by *Sat-1*; 2) 32% homology to the human diastrophic dysplasia sulfate transporter *DTD*; and 3) 45% homology to the human sulfate transporter downregulated in adenoma encoded by *DRA*, is not a transporter of sulfate, but of chloride and iodine. As a result of the level of uncertainty involving a functional assignment of metabolic genes based on homology between known and unknown genes, Scott et al. state (page 441, first column, fourth paragraph):

> "These results underscore the importance of confirming function of newly identified gene products even when database searches reveal significant homology to proteins of known function"

In the instant case, the specification only provide an percentage homology of the polypeptide encoded by the claimed nucleic acid with other known methionine adenosyltransferase or putative methionine adenosyltransferase, but fail to demonstrate the function of a methionine adenosyltransferase of the polypeptide and/or analyze the sequence and/or structural conservation of the claimed sequence as compared to those of known methionine adenosyltransferase.

Furthermore, claims 1-3 are also drawn to nucleic acid encoding a fragment of maize or soybean methionine adenosyltransferase, but the specification does not describe which fragment, what is a core structure required for the fragment, and consequently does not enable one skilled in the art how to use the fragment as a maize or soybean methionine adenosyltransferase .

In summary, the instant specification does not describe the invention in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed nucleic acid as one encoding a maize or soybean methionine adenosyltransferase.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> **(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.**

Claim 1 is rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Everett et al. (Nature Genetics *17*, 411-422, 1997).

Claim 1 is drawn to nucleic acid encoding methionine adenosyltransferase or a fragment thereof. Since the specification does not clearly define the term "fragment", any ONE amino acid residue from the enzyme is interpreted as a fragment thereof. Since it is well-known in the art that maize or soybean polypeptides are initiated with, and contains, an methionine, the methionine residue is interpreted a fragment of a maize or soybean methionine adenosyltransferase. Everett et al. disclose a nucleic acid encoding pendrin comprising several methionine residues. See page 416.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to: Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou, Ph.D.
Patent Examiner

MICHAEL BORIN, PH.D
PRIMARY EXAMINER